

BACKFILE DOCUMENT INDEX SHEET



A DOCPHOENIX

APPL PARTS

IMIS	
Internal Misc. Paper	
LET.	
Misc. Incoming Letter	
371P	PCT Papers in a 371 Application
A...	Amendment Including Elections
ABST	Abstract
ADS	Application Data Sheet
AF/D	Affidavit or Exhibit Received
APPENDIX	Appendix
ARTIFACT	Artifact
BIB	Bib Data Sheet
CLM	Claim
COMPUTER	Computer Program Listing
CRFL	All CRF Papers for Backfile
DIST	Terminal Disclaimer Filed
DRW	Drawings
FOR	Foreign Reference
FRPR	Foreign Priority Papers
IDS	IDS
	IDS Including 1449

Internal

SRNT	
Examiner Search Notes	
CLMPTO	PTO Prepared Complete Claim Set

NPL	Non-Patent Literature
OATH	Oath or Declaration
PET.	Petition
RETMAL	Mail Returned by USPS
SEQLIST	Sequence Listing
SPEC	Specification
SPEC NO	Specification Not in English
TRNA	Transmittal New Application

CTNF	Count Non-Final
CTRS	Count Restriction
EXIN	Examiner Interview
M903	DO/EO Acceptance
M905	DO/EO Missing Requirement
NFDR	Formal Drawing Required
NOA	Notice of Allowance
PETDEC	Petition Decision

OUTGOING

CTMS	Misc. Office Action
1449	Signed 1449
892	892
ABN	Abandonment
APDEC	Board of Appeals Decision
APEA	Examiner Answer
CTAV	Count Advisory Action
CTEQ	Count Ex parte Quayle
CTFR	Count Final Rejection

INCOMING

AP.B	Appeal Brief
C.AD	Change of Address
N/AP	Notice of Appeal
PA..	Change in Power of Attorney
REM	Applicant Remarks in Amendment
XT/	Extension of Time filed separate

File Wrapper

FWCLM	File Wrapper Claim
IIFW	File Wrapper Issue Information
SRFW	File Wrapper Search Info

Office Action Summary	Application No.	Applicant(s)	
	09/696,872	ROTHMAN, JAMES E.	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 February 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 20-26, 28-35, 37 and 44-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 20-26, 28-35, 37, and 44-75 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response, on February 24, 2003, Paper No. 11, to the first Office Action on the Merits of this case is acknowledged. It is acknowledged that applicants have cancelled Claims 27 and 36, amended Claims 20-26, 28-35, and 37, and added Claims 44-75. Claims 20-26, 28-35, 37 and 44-75 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 20-26, 28, 44, 46, 48, 50-56, 72, and 74 drawn to methods for increasing the secretion of a protein by a cell, classified in class 435, subclass 7.2.
- II. Claims 29, in part, 30-35, 37, 45, 47, 49, 57, 59-71, 73, and 75, drawn to a method for promoting the release of a heat shock protein/antigenic peptide complex from a cell, classified in class 424, subclass 278.1.
- III. Claims 29, in part, and 58, drawn to a method for promoting the release of a heat shock protein/antigenic peptide complex from a cell including introducing a nucleic acid encoding the heat shock protein, classified in class 424, subclass 278.1.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Also, product and process inventions are distinct if any of the following can be shown: (1) that the process as claimed can be used to make another and materially different product, (2) that the product claimed can be used in a materially different process of using that product, or (3) that the product claimed can be made by another and

materially different process (MPEP § 806.05(h)). These inventions are different or distinct for the following reasons.

The methods of Inventions I and II are independent as they produce different results. The methods of Inventions I and III are independent as, they produce different results. The methods of Invention II and Inventions III are independent because they comprise different steps and utilize different products.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Claims 23-26, 28, 44 and 46 as well as 32-35, 37, and 45 include the following species of oligomerization domain:

Pentamerization domain,

Trimerization domain,

Derived from a cartilage matrix protein,

Derived from phospholamban,

Derived from thrombospondin,

TSP3,

TSP4,

SEQ ID NO: 1,

SEQ ID NO: 2,

SEQ ID NO: 7,

SEQ ID NO: 3,

SEQ ID NO: 4,

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SEQ ID NO: 5, and

SEQ ID NO: 6.

These species of Claims 23-26, 28, and 44, and 46 as well as 32-35, 37, and 45 are patentably distinct because they are physically and functionally distinct chemical entities.

Claims 48 and 49 as well as 75 and 75 include the following species of KDELR inhibitor protein:

SEQ ID NO: 13 or the protein encoded by SEQ ID NO: 14,

SEQ ID NO: 15 or the protein encoded by SEQ ID NO: 16,

SEQ ID NO: 17 or the protein encoded by SEQ ID NO: 18,

SEQ ID NO: 19 or the protein encoded by SEQ ID NO: 20,

SEQ ID NO: 21 or the protein encoded by SEQ ID NO: 22,

SEQ ID NO: 23 or the protein encoded by SEQ ID NO: 24,

SEQ ID NO: 25 or the protein encoded by SEQ ID NO: 26,

SEQ ID NO: 27 or the protein encoded by SEQ ID NO: 28,

SEQ ID NO: 29 or the protein encoded by SEQ ID NO: 30, and

SEQ ID NO: 34 or the protein encoded by SEQ ID NO: 35.

These species of Claims 48 and 49 as well as 75 and 75 are patentably distinct because they are physically and functionally distinct chemical entities.

Claims 50-53, 56 as well as 57 and 59 includes the following species of methods for expressing the protein in a cell:

Naturally occurring,

Expressed as a result of introduction of a nucleic acid,

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Introducing a nucleic acid molecule encoding the protein, and

Introducing the protein into the cell using microvesicles.

These species of Claims 50-53, 56 as well as 57 and 59 are patentably distinct because they are methods that utilize different products, use different steps, and/or produce different results.

Claims 54 and 55 as well as 60 and 61 include the following species of moiety conjugated to the KDElr inhibitor:

Sugar,

Folate,

Insulin,

Transferrin,

PEG, and

Antigenic peptide.

These species of Claims 54 and 55 as well as 60 and 61 are patentably distinct because they are physically and functionally distinct chemical entities.

Claims 62-71 include the following species of cancer, infective agent, or oncogene-associated protein to be released with the KDELr inhibitor:

Sarcoma,

Lymphoma,

Leukemia,

Melanoma,

Breast cancer,

Prostate cancer

Ovarian cancer,

Cervical cancer,

Uterine cancer,

Colon cancer,

Lung cancer,

Glioblastoma,

Astrocytoma,

Virus,

Protozoan,

Mycoplasma,

Fungus,

Yeast,

Parasite,

Prion,

Papilloma,

Herpes,

Retrovirus,

Hepatitis,

Influenza,

Rhinovirus,

Respiratory syncitia virus,

Cytomegalovirus

Adenovirus,

HIV1,

HIV2,

Salmonella,

Staphylococcus,

Streptococcus,

Enterococcus,

Clostridium,

Escherichia,

Klebsiella,

Vibrio,

Mycobacterium,

Tumor suppressor gene,

Defective p53,

Oncogene,

Ras,

Src,

Erb,

Fos,

Abl, and

myc.

These species of Claims 62-71 are patentably distinct because they are physically and functionally distinct chemical entities.

Claims 72 as well as 73 include the following species of sequences at the carboxy-terminus of the KDELr inhibitor: X-Asp-Glu-Leu where X is:

Lys,

His, and

Asp.

These species of Claims 72 and 73 are patentably distinct because they are physically and functionally distinct chemical entities.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of oligomerization domain, KDELr inhibitor protein, method for expressing the protein, conjugated moiety, cancer, infective agent, or oncogene-associated protein to be released, and carboxy-terminus of the KDELr inhibitor, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Thus, applicant is required to elect one of Inventions I, II, and III and one species within each category described above. Currently, Claims 20, 21, 23, 24, 25, 26, 29, 30, 32, 33, 35, 54, 55, 58, 60-75 are generic.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 9:30-6 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan Lee Swope, Ph.D.


REBECCA E. PROUTY
PRIMARY EXAMINER
OCT 17 2009
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